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| Document Type:<br>STANDARD OPERATING PROCEDURE                               |                          | Document Number:<br>SOP-OP-003.0 |
| Document Title: <b>Instrument Installation, Maintenance, and Calibration</b> |                          |                                  |
| Author:<br>Jane Doe                                                          | Approval Signature/Date: | Page 1 of 6                      |
| Reviewer:<br>John Doe                                                        | Approval Signature/Date: | Effective Date:<br>03Feb2023     |
| Approver:<br>Facility Director's Name                                        | Approval Signature/Date: | Revision:<br>V4                  |

## 1.0 PURPOSE

This policy documents the maintenance and calibration requirements for all flow cytometry analyzers and cell sorters maintained by the Shared Resource Laboratory (SRL) at the University.

## 2.0 EQUIPMENT

| Equipment Name      | Manufacturer   | Serial # |
|---------------------|----------------|----------|
| BD Aria II          | BD Biosciences | N/A      |
| BD Aria Fusion      | BD Biosciences | N/A      |
| BD Symphony S6      | BD Biosciences | N/A      |
| BD Symphony A1      | BD Biosciences | N/A      |
| BD Symphony A3 lite | BD Biosciences | N/A      |
| BD Symphony A5      | BD Biosciences | N/A      |
| BD Symphony A5 SE   | BD Biosciences | N/A      |
| BD LSR II           | BD Biosciences | N/A      |
| BD LSRFortessa      | BD Biosciences | N/A      |
| USB Flash drive     | N/A            | N/A      |

## 3.0 RESPONSIBILITIES

- 3.1. It is the responsibility of the SRL to ensure that equipment designated for public use is maintained in good condition and available for scheduling whenever possible.
- 3.2. It is the responsibility of the SRL to maintain records of equipment installation, calibration, maintenance, and non-routine repairs.
- 3.3. It is the responsibility of the user to ensure equipment is clean, calibrated, and in working order prior to instrument usage.

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- 3.4. It is the responsibility of the user to promptly report any equipment malfunctions to the SRL staff.

#### 4.0 GENERAL

- 4.1. All non-daily maintenance and calibration actions must be documented within the relevant folder on the MaintenanceTRAK cloud storage.

#### 5.0 PROCEDURES

##### 5.1. Installation

- 5.1.1. All installation and procedures (i.e. configuration setup, instrument baseline, etc.) must be completed by the manufacturer before the instrument is made available for public use.
- 5.1.2. Upon purchase of a new flow cytometer, the SRL will collaborate with the manufacturer to ensure successful instrument installation.
- 5.1.3. The IT team is required to connect the instrument to the network, set up the cloud server for data export, and restrict access to only trained users.
- 5.1.4. Equipment accessories must be provided by the SRL. This may include, but is not limited to the following:
- 5.1.4.1. Vortex, Kimwipes, labeled wash bottles containing the relevant reagents (see the instrument-specific startup SOP), 5mL polystyrene tubes, daily QC beads, sheath fluid, bleach, paper towels, tube rack, and a sharpie.
- 5.1.5. The instrument must be added to the sheath delivery supply list.
- 5.1.6. Upon completion of all installation requirements, the machine will be added to the scheduler for use by all users with the appropriate training level.
- 5.1.7. If a new training class is required for the instrument, the SRL staff will add this training class to the training portal.

##### 5.2. Daily Maintenance

- 5.2.1. Every morning Monday-Friday, the SRL staff checks the scheduling system to see which instruments are being used for the day. Instrument startup/maintenance and quality control/performance checks are done by staff for each instrument that has a scheduled user reservation. Each equipment model's startup and performance check are unique. For details on model specific start up, reference the model's relevant SOP-OP-002.X sub document.
- 5.2.2. Daily maintenance and performance check must be performed under the "QC" project when logging into the server. When logging out, all QC data (i.e. CS&T reports) will automatically upload to the appropriate folder in the cloud server for data retention.

##### 5.3. New Bead Lots

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- 5.3.1. Beads for daily maintenance (i.e. CS&T beads) should be bulk ordered with enough advance notice to ensure that the validation of the new lot can be performed on all instruments before old lot expires and/or the inventory runs out.
- 5.3.2. When a new lot of beads are received, the lot is validated (i.e. re-baselined or reset target values) prior to usage for daily maintenance and QC.
- 5.3.3. **For Symphony cytometers, SRL staff should always attempt to reset target values before re-baselining the instrument when receiving a new lot of beads.** This retains the MFI values between bead lots, prevents the loss of the determined optimal voltages, and prevents the loss of saved application settings in user experiments.
- 5.3.4. **For non-Symphony cytometers,** download the new bead lot specifications by locating the lot-specific file on the BD website and downloading it to a removable flash drive. Skip to step 5.3.5. for all other cytometers.
- 5.3.4.1. Details on the file download location can be found on the product insert.
- 5.3.4.2. Cytometer PCs are not connected to the internet. This file must be downloaded from a separate computer before uploading to the cytometer PC.
- 5.3.4.3. Bring the flash drive with the downloaded bead lot file and a USB blocker/remover tool to the cytometer workstation.
- 5.3.5. Log into the cytometer by tapping your ID Card on the server card reader. Select QC as the project to ensure the files are saved in the appropriate QC folder. Log into the Diva software using the administrator account.
- User: Administrator  
Password: XXXXX
- 5.3.6. Before continuing, ensure the machine has been warmed up and cleaned thoroughly. The machine must be at optimal performance before continuing.
- 5.3.7. Run a CS&T Performance Check on the instrument using the current in-use bead lot to confirm cytometer is operating properly. This workflow must pass successfully before continuing. For details, reference the model's relevant SOP-OP-002.X sub document.
- 5.3.8. Select the dropdown menu *Cytometer* → *CST*. A new CST window will appear. In this window select the dropdown menu *Tools* → *Bead lots*.
- 5.3.9. For non-Symphony instruments:
- 1) Select the *Import* button. Take note of the file pathway location that opens.
  - 2) Close this window. In the computer's file explorer, copy and paste the downloaded bead lot information from the flash drive folder to the corresponding bead lot folder.

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- 3) Return to the bead lot window and select the Import button again. The new bead lot file will be available. Select this file and choose Import. Close the bead lot window to return to the CST window.

5.3.10. For Symphony Instruments:

- 1) Select the *New* button at the bottom of the window.
- 2) Input the following information using values on the bottle (not on the box):  
 Part Number – The catalog number of the new bead lot.  
 Lot ID – The lot number of the bead lot vial.  
 Expiration – Expiration date of the new bead lot vial.

5.3.11. Under the *Setup Bead* section, choose the *Characterize* dropdown and select *Reset Target Values*.

5.3.12. A Setup Control window will open. Check the box for *load tube manually*. Ensure that the *Setup beads* section has the correct lot numbers for the old and new bead selections.

5.3.13. Verify that the configuration in the software is identical to the physical configuration of the cytometer. If multiple configurations are used on the instrument, the Reset Target Values workflow must be performed for each configuration.

5.3.14. Label two 5mL FACS tubes: one with the new bead lot number and the other with the old bead lot number. Vortex both bead vials vigorously. Add 500uL of sheath fluid to each FACS tube. Then, add 3 drops of beads to the appropriate lot-specific labeled tube and vortex. *Note: New dilutions of beads should always be used when performing this workflow.*

5.3.15. For Fortessas, ensure that the fine adjustment knob is set to the middle (5 rotations). For Symphonies, the digital display on the cytometer should read 250. Use up/down arrow buttons located on the analyzer to adjust this.

5.3.16. Select *Run* in the software to initiate the Reset Target Values process. A prompt will populate requesting the old lot of beads be placed on the sample injection port (SIP). Do this, then select *OK*. For analyzers, click Run and Low speed on cytometer.

5.3.17. During the process, the software will populate a prompt requesting the operator to load the next bead lot tube. Place the new bead lot on the SIP.

5.3.17.1. Several other messages may appear throughout the process. Select only the *Continue* or *Next* buttons each time this occurs.

5.3.18. Once complete, ensure that there are no warning prompts in the report. If there are warnings, take the necessary steps to fix the issue if possible. If not, continue to the end of this section.

5.3.19. Once the new lot has been validated, rerun CST by selecting *Check Performance* in the *Characterize* drop down in the CS&T window. Select *Run* and *OK* to perform the daily QC using the new bead lot.

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- 5.3.20. When complete, the new bead lot may be used for daily QC. Use the instrument's model specific startup and QC SOP to clean and close out of the cytometer.
- 5.4. Instrument Re-baselining
- 5.4.1. CS&T software will prompt for a new baseline every 6-months. Re-baselining can be done as part of routine maintenance, after a major service was completed, and/or when resetting target values fails.
- 5.4.2. **Symphony cytometers should not be re-baselined without a Flow Core Director's approval, as they contain volttration values in the software.** Instead, perform the *Reset Target Channels* procedures using the instructions for Symphony instruments (see above).
- 5.4.2.1. If the same lot is used for both "new" and "old" bead lot files, enter lot number 00001. Increase this consecutively until a new bead lot is used (i.e. 00002, 00003, etc). Enter catalog number and expiration date.
- 5.4.3. To re-baseline an instrument, follow all steps for resetting target values with the following exceptions:
- 5.4.3.1. Select *Baseline* in the Characterize window during set up.
- 5.4.3.2. Dilute only the new bead lot at the recommended dilution ratio specified in the product insert for baselining (typically 3 drops in 500µL).
- 5.4.3.3. No prompt will populate to direct the operator to switch bead lots during the baselining workflow.
- 5.4.4. When complete, follow the model's relevant SOP-OP-002.X sub document to ensure it is cleaned and shut down properly.
- 5.5. Preventative Maintenance
- 5.5.1. All instruments require preventative maintenance actions to be taken annually. The preventative maintenance is scheduled and completed by the manufacturer.
- 5.5.2. LSR II, Aria, Symphony, and Fortessa instruments also require biannual maintenance tasks.
- 5.5.3. Required preventative maintenance tasks are outlined in each instrument's service manuals. This may include but are not limited to: laser realignment, instrument cleaning, changing filters, replacing sample lines, replacing deteriorating parts, and HTS maintenance.
- 5.5.4. Preventative maintenance tasks are performed by the manufacturer using the preventative maintenance kit provided by the manufacturer.
- 5.6. Non-Routine Maintenance
- 5.6.1. In the event of an equipment malfunction, the SRL should try to address the issue in-house before contacting the manufacturer. Any actions taken should be documented in the maintenance logs located on the MaintenanceTRAK cloud server.

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5.6.2. In the event of an equipment malfunction that cannot be addressed in-house, the manufacturer should be contacted for repairs. All repairs performed by the local service engineer require a written report stating what actions were taken to address the malfunction.

5.6.3. Documentation of service calls should be recorded in the maintenance log located on the MaintenanceTRAK cloud server. This information must include: the issue encountered, date of service, the resolution of the issue, and the licensed contractor's name.

5.6.4. After repair completion, the instrument must be verified for performance before being made available for operational use.

#### 5.7. Instrument Interruption

5.7.1. If the instrument will be taken out of service for any amount of time:

5.7.1.1. The SRL must notify any user/s who have a scheduled reservation on that instrument.

5.7.1.2. The SRL must block off the machine's scheduling availability until repaired.

5.7.1.3. The user must reschedule their appointment to a different instrument.

5.7.2. If the instrument will be permanently taken out of service:

5.7.2.1. The SRL must notify all users.

5.7.2.2. The SRL must remove the instrument from the scheduler.

5.7.2.3. The SRL must arrange to relocate the equipment to be discarded.

## 6.0 REFERENCES

6.1. N/A

## 7.0 REVISIONS

7.1. 20230203 – Jane Doe – Version 1

7.2. 20240405 – Jane Doe – Version 2 Addition of preventative maintenance upload requirements. Thoroughly outlined details for a new CS&T lot data file upload.

7.3. 20240510 – Jane Doe – Version 3 Added new CS&T bead lot details for Symphony instruments.

7.4. 20251027 – John Doe – Version 4 Added Diva Admin password and additional clarifications.